EXHIBIT 14

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.,

a Massachusetts Corporation

Plaintiff

-VS
CA No. 04-12457-PBS

Pages 1 - 87

ARTHREX, INC.,

a Delaware Corporation, et al,)

Defendant

MARKMAN HEARING

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

APPEARANCES:

DIANNE B. ELDERKIN, ESQ., LYNN A. MALINOSKI, ESQ., and MICHAEL J. BONELLA, ESQ., Woodcock Washburn, One Liberty Place, 47th Floor, Philadelphia, Pennsylvania, 19103, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts September 26, 2006, 2:00 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
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Page 2 1 PROCEEDINGS THE CLERK: The case of DePuy Mitek, Incorporated 3 V. Arthrex, Incorporated, et al, Civil Action No. 04-12457, will now be heard before this Court. Will counsel please 4 5 identify themselves for the record. 6 MS. ELDERKIN: Yes, your Honor. I'm Dianne 7 Elderkin on behalf of DePuy Mitek. I have my colleagues Michael Bonella and Lynn Malinoski with me here. THE COURT: All right. 10 MR. SABER: Good afternoon, your Honor. My name is 11 Charles Saber from Dickstein Shapiro for defendants Arthrex 12 and Pearsalls, and with me is my colleague Sal Tamburo. 13 THE COURT: Thank you. 14 MR. SABER: Thank you, your Honor. 15 THE COURT: So we should begin with claim 16 construction. I'm thinking we'll go at least two hours. 17 don't know if you had any evidence that either of you were 18 going to be putting on. 19 MS. ELDERKIN: No, just argument today, your Honor. 20 MR. SABER: That's right. We had discussed this 21 beforehand and had agreed it was just going to be 22 argumentation. 23 THE COURT: Okay. 24 MS. ELDERKIN: I'm prepared to argue the claim 25 construction for DePuy Mitek. We have copies of our

Page 3 Powerpoint slides. May I --That would be wonderful. Do you have THE COURT: 3 an extra one for the law clerk who would be working on this? MS. ELDERKIN: I don't think I have quite that 5 many. 6 THE COURT: Let me say, I'm not that familiar with 7 all of you, but it's the practice here -- and I know it's extremely confusing when you file electronically -- when 9 there are records of the volume that this was, is to also 10 provide courtesy copies. So I apologize. As I started to 11 prepare last week, it occurred to me that it would consume my 12 printers for all of a week if I tried to print everything 13 out, and I only recently -- well, I think someone submitted 14 Friday and someone on Monday, so I by no means have had time 15 to go through this record. 16 MS. ELDERKIN: We understand. 17 MR. SABER: And we perfectly understand, your 18 Honor. 19 THE COURT: I don't know what they're doing in 20 other districts, but here it's pretty much the standard. 21 MS. ELDERKIN: It's certainly understandable. 22 MR. SABER: I think, with the electronic filings 23 now, we're all just kind of getting used to the rules. 24 THE COURT: All right, so if there's doubt again, 25 just give Mr. Alba a call, but in general, I'm happy to do

- all your normal filings, you know, the routine stuff. But
- when it's this big, you really need to give me a courtesy
- 3 copy. But we've got it. I think I've got both sides, so
- 4 here we go.
- MS. ELDERKIN: Your Honor, again, I'm Dianne
- 6 Elderkin. If we get to any of the summary judgment motions
- today, my colleagues are going to be prepared to argue the
- 8 inequitable conduct and the validity motion as well.
- 9 THE COURT: Fine.
- MS. ELDERKIN: But I'm going to start with claim
- construction at your suggestion.
- The patent in suit here is the Hunter '446 patent,
- and, just briefly, it has to do with a surgical suture. And
- if you look at the background of the Hunter patent, it talks
- about the desire to produce an improved suture with improved
- properties. And there's some talk in the background section
- of what was done in the prior art, and there were braided
- sutures known in the prior art.
- THE COURT: When you say "background," do you mean
- the specification?
- MS. ELDERKIN: Yes, the background part of the
- specification. There were sutures made from certain braided
- constructions known in the prior art, but they were not
- ideal, and there was a desire to prepare an improved suture,
- and that's what the Hunter '446 patent discloses and claims.

1 Now, the claims, the patent instructed to a surgical suture that is made from a heterogenous braid. 3 what's this heterogenous braid? Well, the claims in the disclosure talk about this braid having first and second sets 5 of continuous and discrete yarns. So you can see the red lines here going to one set of the yarns, the other red line 7 going to the second set of the yarns. Those lines are discrete, they're separate; and that you have in this braided 9 construction at least one yarn from the first set that's in 10 direct intertwining contact with a yarn from the second set. 11 And you might think, well, gee it says braided, it 12 says intertwining contact, wouldn't anything in a braided 13 construction be an intertwining contact? And the answer is 14 "no, not necessarily." There are prior art sutures 15 disclosed that have a core of one material and then a braid 16 around it of another material that's a braided construction, 17 but the yarns are not in direct intertwining contact with one 18 another. 19 The claims also specify the materials from which 20 this first and second set of yarns should be constructed, and 21 as is shown here, those are polymeric materials. Those two-, 22 three-, and four-letter abbreviations stand for different 23 polymeric materials. The first set of yarns is made from 24 that one group of materials. The second group of yarns are 25 made from the second group of materials. And, importantly,

Page 6 the yarn is made of a plurality of filaments of those materials. So it's like a yarn that you might be knitting a sweater with. Each yarn, you can take it apart, it has many, 3 many filaments in it, as opposed to being a monofilament, a 5 single large filament making up the yarn. So that's like the 6 very broad summary of the invention in the Hunter '446 7 patent. This is a recitation of Claim 1 of the patent. 9 There's only one independent claim, and, fortunately, there 10 are only two claims here that are in dispute. They're 11 highlighted in red here. Those terms are "consisting 12 essentially of and "PE." And this claim recites pretty much 13 what I've just gone through, that it's a surgical suture --14 THE COURT: Right. 15 MS. ELDERKIN: -- a heterogenous braid. Okay, I 16 won't go through that again. 17 When you read the patent, it makes it clear that an 18 important aspect of this invention is mechanically blending 19 these yarns of different materials so that you can achieve 20 the beneficial properties of both of the yarns. This is 21 stated in the specification at Column 2 where it talks about 22 tailoring the physical and biological properties of the braid 23 by using these different materials and varying the types and 24 proportions of materials. It's referred to again in Column 3 25 where it talks about direct mechanical blending of these

Page 7 individual and dissimilar yarns to achieve maximum degree of mechanical blending. And so that's an important aspect of 3 the invention. Now, if you've had a chance to look at any of the 5 briefs, you know that an issue that pervades the claim 6 construction dispute, and also the infringement dispute, is 7 the parties' disagreement over whether the materials recited in the claim, those polymeric materials, must have specific 9 properties. Mitek says they do not have to have specific 10 properties; Arthrex says that they do. So before I even get 11 into specifics of claim construction, I want to look at the 12 specification for you and show you, what does the 13 specification say? 14 THE COURT: Well, let me just say that it strikes 15 me that there are two completely different kinds of issues 16 One is what "PE" means, which strikes me as a much 17 more straightforward kind of analysis than what "consisting 18 essentially of " means. 19 MS. ELDERKIN: Yes, we would agree that the 20 analysis of what "PE" means is very straightforward, and that 21 it has a plain and ordinary meaning to one of skill in the 22 art, and that there's no need to try to read in properties. 23 THE COURT: So, as I understand it, you've referred 24 to scientific texts which refer to it as a generic --

Correct.

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MS. ELDERKIN:

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               THE COURT: -- what would you call it, a polymer?
               MS. ELDERKIN: Right, right.
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               THE COURT: A generic name that picks up light
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     molecule, heavy molecule, et cetera.
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               MS. ELDERKIN:
                              Right.
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               THE COURT: And you essentially say through two
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     experts that that's what someone of ordinary skill in the art
     would have felt, and you pick that up in a textbook kind of
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     way.
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               MS. ELDERKIN:
                              Right.
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               THE COURT: And, as I see it, there's no opposing
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     expert on that particular issue. Did I miss it, because I
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     have this thick volume, that someone of ordinary skill in the
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     art would have understood it to mean something else?
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     just turning because I want to get to the one that I think is
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     a whole lot harder, which is the "consisting essentially of."
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               MR. SABER: Well, there is a dispute, your Honor,
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     about what's shown in those textbooks because it's not at all
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     clear.
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               THE COURT: I got this huge crate from you
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     yesterday.
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               MR. SABER: I understand.
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               THE COURT: Is there something in there? Is there
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     an expert who disagrees with what a person of ordinary skill
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     in the art would have thought the initials "PE" meant?
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               MR. SABER: Well, certainly, your Honor, there is.
               THE COURT: All right, because as I understand it,
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     I think you can look at dictionaries. I disagree that you
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             It just doesn't have the glorified, exalted position
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     that it had under Texas Digital, but it is still an
     appropriate form to look at. So who is your expert of
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     ordinary skill in the art who says that it doesn't mean a
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     generic term, that it had a specific term?
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               MR. SABER: Well, Dr. Mukherjee, who in his reports
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     opined that, you know, from his review of the specification,
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     that what the term "PE" would mean would be something that is
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     not this generic term, and --
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               THE COURT: So where is that attached to? There's
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     a whole --
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               MR. SABER: Yes, and I can't cite you exactly where
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     it is.
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               THE COURT: So you're saying he says that PE means
     what to someone -- what is the time frame? Right, it's the
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     time of the filing of the application? Is that what it is?
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               MR. SABER:
                           That's correct.
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               MS. ELDERKIN: Yes, your Honor.
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               THE COURT: Which was when?
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               MR. SABER: '92.
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               THE COURT: 1992. So in 1992, at the time of the
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     filing of the application, does he say it is not a generic
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Page 10 1 term? MR. SABER: Well, he doesn't get into the 3 dictionary except --THE COURT: I'm not talking about dictionary. 5 talking about a person of ordinary skill in the art in 6 1992. 7 MR. SABER: Right, and he does that by reading the 8 specification. It's his understanding of what it means in 9 the specification. So I'm not sure if that's being 10 responsive to your question, your Honor. 11 THE COURT: So, in other words, he's basically not 12 disagreeing that if you just took the term "PE" in 1992, that 13 a person of ordinary skill in the art would have understood 14 it to be a generic term. What he's trying to say is, in the 15 context of the specification, I should understand it 16 differently? 17 MR. SABER: Well, two things. He says that latter 18 With respect to the former thing, it's not like he 19 offers his own dictionary definitions. He doesn't do that. 20 THE COURT: You keep saying dictionary, but these 21 people have their -- I'm assuming he's a chemist, right? 22 MR. SABER: His background is in suture, that's 23 correct. 24 THE COURT: So he knows what a polymer is and --25 MR. SABER: Of course, of course.

Page 11 1 THE COURT: Right, all right, so he knows what PE 2 is, I'm assuming. So he's not offering an alternative, that 3 polyethylene in 1992 did not include -- what do you call it? MR. SABER: Ultra-high molecular weight PE, right. 5 THE COURT: He doesn't say that. What he's simply 6 saying is, "I understand the term based on the specification 7 to mean something different." MR. SABER: Right, he does that, your Honor, and he 9 also looks at the evidence that the other side presented on 10 whether there's an ordinary meaning and says it doesn't show 11 That's the point I guess I was trying to say, so he 12 disagrees with it in that sense. 13 THE COURT: Well, does he give some other 14 dictionary meaning? 15 MR. SABER: No, he doesn't. 16 THE COURT: Because I actually went online myself 17 yesterday to see if there was any other meaning. I looked in 18 my own little scientific dictionary they give the judges. 19 looked even in Wickapedia. I looked everywhere to see if 20 there was some separate meaning that I could find, and I 21 looked at these attachments as well as the various expert 22 reports, and it has a generic meaning, unless it was 23 disclaimed somewhere. 24 MR. SABER: Yes, the evidence that the other side 25 put in we don't believe establishes that, and that's what

- 1 Dr. Mukherjee talked about, but he did not offer an
- alternative meaning of the term "PE" apart from the patent.
- THE COURT: It's a molecule, right, with carbons
- 4 and hydrogen atoms and like I learned in science? That's all
- it is, and it just depends on how long the chain is? Do I
- 6 have that basic rudimentary understanding down?
- 7 MR. SABER: To a point, your Honor, that's
- 8 correct. The problem, and, again, I don't want to interrupt
- 9 Ms. Elderkin --
- THE COURT: But am I right, the longer the chain
- is, the heavier it is? Is it basic like that?
- MR. SABER: Like anything else, I'm sure it's more
- complicated than that. But the problem was that the material
- that their expert relied upon used what was called
- source-based identification. He offered two, but only one
- talked about it, and that one said, well, the source-based
- name would include all of these things. But the very, very
- same reference said that's not the end of the story because
- to use just a source-based identification could be really
- confusing as to what we're talking about.
- THE COURT: Sure, because there are subtypes.
- There are light weight and heavy weight, and then, I mean, I
- 23 saw five others.
- MR. SABER: That same publication says, we really
- think you should do this based upon the molecular structure

Page 13 of the product, which, of course, is exactly what the issue is here. So the very piece of evidence that they rely upon 3 to establish this ordinary meaning says it all depends on how you look at it. 5 THE COURT: All right, thank you. So his basic 6 point, as I read his briefs, are, look -- you can disagree 7 with this -- there is a generic meaning to it, but given what the purpose is for this, which is flexibility, that when you 9 deal with the higher-weight stuff, it's not flexible. 10 fact, it's known for its tensile ability. And so he's saying 11 that I shouldn't construe "polyethylene" as a broad term 12 because it actually doesn't fulfill the function that's set 13 forth in the specification. Did I get that right? 14 MR. SABER: Pretty good. 15 So how do you respond to that? THE COURT: 16 MS. ELDERKIN: Well, it's legally wrong, and it's 17 factually wrong. Legally it's wrong because the law is 18 Phillips make it clear, we construe the claim term 19 according to how one skilled in the art would construe it. 20 Its plain and ordinary meaning should take precedence. 21 There is evidence, which we believe is undisputed, 22 that the plain and ordinary meaning of "polyethylene" is just 23 poly-ethylene. There's no reference in the specification to 24 anything else. 25 THE COURT: By the way, none of you defined this

Page 14 term for me, "lubricious." Okay, you must all assume I know what it is, but when you look it up, it actually means 3 different things. MS. ELDERKIN: Oh, really. 5 THE COURT: It can mean wet. It can also just be 6 smooth or slippery. So do you know what it means in this 7 context? MS. ELDERKIN: My understanding is, it means smooth 9 and slippery. 10 MR. SABER: I would agree with that, your Honor. 11 THE COURT: Not necessarily wet? 12 MR. SABER: That's correct. 13 MS. ELDERKIN: Right, right, right. So 14 polyethylene has this plain and ordinary meaning to one 15 skilled in the art. And there is nothing, as we know again 16 from Phillips and other cases, to alter the plain and 17 ordinary meaning. There has to be a very clear and 18 unambiguous disavowal in the patent specification to change 19 that meaning. There is no special definition of PE in the 20 patent. The one place it's used, I believe it's in Column 3, 21 the word "polyethylene" is spelled out and in parens "PE," 22 polyethylene. That's what it means. 23 THE COURT: All right, can we jump to part two 24 which is what I found incredibly -- I do a lot of these

patent cases, and I've actually not had occasion to deal with

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Page 16 of 89 Page 15 the "consisting essentially of" term. And we tried to read some cases on it, and there actually aren't that many, and I had a hard time understanding whether it was a claim construction issue or an infringement issue. In fact, one case says it's some hybrid between the two. MS. ELDERKIN: And, your Honor, I believe it's both. There certainly is a claim construction issue. believe it's for the Court. Of course, what "consisting essentially of means, as you know, it means there can be elements in an infringing device that are not expressly recited in the claim, as long as they don't alter, materially change, the basic and novel characteristics of the invention. THE COURT: And how am I supposed to know what those are? MS. ELDERKIN: Well, we believe that the novel and basic characteristics of the invention, that that is a claim construction issue, and I'm prepared to explain to you -- you know, the parties have competing definitions of what those novel and basic characteristics are. And then it will be an issue for the jury, or for you on summary judgment, to determine whether -- and the issue here is the coating on

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characteristics.

THE COURT: When you say "materially affect," I was having trouble understanding it because primarily we're

FiberWire suture -- materially affects those basic and novel

Page 16 talking about the coatings, right? MS. ELDERKIN: Right. 3 THE COURT: And the coatings make it more slippery, 4 maybe. 5 MS. ELDERKIN: Purportedly, maybe. 6 THE COURT: Okay, and lubricous. So they 7 essentially enhance the invention. MS. ELDERKIN: Right. THE COURT: All right? So originally I had thought 10 "materially affect the novel and basic characteristics" 11 meant somehow change them. You used the word "alter," and 12 one case uses the word "alter," but the case law doesn't 13 consistently use the word "alter." They usually use the word 14 "materially affect." 15 MS. ELDERKIN: Materially affect, right. 16 THE COURT: So if it significantly improves on the 17 invention, materially improves on, let's say, the 18 flexibility, would that be improving the novel and basic 19 characteristics? 20 MS. ELDERKIN: Well, it's obviously so 21 fact-intensive; you know, how much change is there, how much 22 alteration? 23 THE COURT: But if it's materially improved, you'd 24 say that that fell within this "consisting essentially of," 25 even if it's not a detracting from?

- MS. ELDERKIN: It certainly could. And a lot
- 2 obviously depends on, what are those novel and basic
- 3 characteristics? Now, Arthrex argues that those
- 4 characteristics are flexibility, handleability, and not
- diminishing the strength of the suture. But our position is
- 6 that that is much too narrow a definition, that the basic and
- 7 novel characteristics of this invention encompass this
- 8 concept that I discussed earlier about mechanical blending of
- ⁹ the properties of the two discrete sets of yarns.
- Now, it may very well be that the effects of those
- yarns, one enhances pliability and one enhances strength, but
- the patent specification is not limited to that. The
- preferred embodiments are talked about in terms of, well, gee
- in some preferred embodiments, you might take a weak material
- that's slippery or lubricous and --
- THE COURT: Well, is there evidence that just the
- yarn piece of it, you know, the braiding of the yarn, is
- 18 novel and basic?
- MS. ELDERKIN: That the braiding of the yarn --
- THE COURT: In other words, what makes this novel,
- this invention?
- MS. ELDERKIN: Well, I don't mean to be trite, but
- everything in the claim, which is the concept of a braided
- construction, two discrete yarns.
- THE COURT: So no suture before it ever had that?

- MS. ELDERKIN: Not everything in the claim, no
- suture before this had a braided construction where the yarns
- were in intertwining contact, and the yarns were the
- 4 materials we cited in this claim, and the yarns were made of
- the multifilaments as recited in this claim. And I don't
- 6 want to mislead you. There were certainly a lot of braided
- ⁷ sutures in the prior art, but none having this particular
- 8 configuration, and this concept of mechanical blending where
- 9 I can take a yarn of one material and a yarn of another
- material, if I put them together in this particular
- 11 configuration --
- THE COURT: So no other suture had this blending of
- different materials?
- MS. ELDERKIN: None that we're aware of, your
- 15 Honor, none that have been cited in the Patent Office and
- none that Arthrex has cited in this lawsuit.
- THE COURT: So no matter what the materials are,
- there are none that had dissimilar braids?
- MS. ELDERKIN: In this particular configuration and
- with these materials. I don't want to misspeak. I can't say
- that there's none that have them.
- THE COURT: So are you going to walk me through
- what -- I don't want to go through PE. I mean, that really
- seems more straightforward, but I must say, this I found
- difficult. And then I'll give you --

Page 19 1 MR. SABER: Sure. MS. ELDERKIN: Okay, if I may, I'm going to stay 3 with this slide. It relates to both PE and "consisting 4 essentially of. But it's important to understand what is in 5 the specification on which Arthrex is relying to try to pull out this requirement that the first materials have to be weak and the second materials have to be strong, so that the novel 7 and basic characteristics of the invention are the strong yet 9 pliable suture. 10 Now, we don't disagree that the patent 11 specification does disclose that the first material, the 12 materials in the first set, can be lubricious. And that's 13 what you talked about, they can be somewhat slippery. And it 14 says here -- this is in Column 4 -- that they can act as 15 lubricating yarns to improve the overall pliability. But not 16 just pliability, or compliance, and surface lubricity of the 17 heterogenous braid, but just because the first fiber-forming 18 materials, those materials in the first class, can be 19 lubricious doesn't mean that they also have to be weak or 20 that they have to produce a pliable braid. Let's see --21 THE COURT: Well, what's the difference between 22 pliable and lubricious? 23 MS. ELDERKIN: A lubricious material is something 24 that's slick and slippery. A pliable material is something 25 that bends easily.

1 THE COURT: So at least you would say 2 conceivably -- well, I suppose that's right, you could have 3 something slippery that you can't bend, all right. MS. ELDERKIN: Right. Arthrex says in its brief, 5 they talk about these first seven polymers, and it says that 6 they're lubricious. And it says, the specification 7 unambiguously states that "A braid that's made solely of these lubricious yarns will result in a highly pliable 9 braid," and they repeat this over and over again as a basis 10 for their argument that the novel and basic characteristics 11 include this concept that the braid must be pliable. 12 that's not what the specification says. If you look at where 13 the specification talks about this in Column 2, it says, "If 14 fibers composed of highly lubricious polymers are used in the 15 traditional manner -- i.e., not necessarily according to this invention -- then a highly pliable braid can be prepared." 16 17 But there's nothing definitive in the patent that says, if 18 you have a lubricious first fiber-forming material, you will 19 get a pliable braid. 20 And again elsewhere in their brief Arthrex says, 21 "The specification teaches that while this braid made 22 entirely of lubricious materials would make a highly pliable 23 braid, the braid will be weak and unusable." But, again, 24 that's not what the specification says. If you look at 25 Column 4, it says, "In most cases, these braids will be

- 1 relatively weak and unusable." It's not a definitive
- 2 statement that the braids made with these materials will
- necessarily be weak and unusable.
- 4 And then, finally, Arthrex tries to read into this
- 5 a requirement that this first material which is lubricious
- 6 must also be relatively weak; that is, weaker than the second
- group of materials. But that again is not the case. There
- 8 is no such disclosure in the patent. And indeed other
- 9 materials that are recited in that list of the first
- 10 fiber-forming materials -- for example, the PVDF and the PP,
- which is the polypropylene --
- 12 THE COURT: How do I know that? How do I know
- 13 that?
- MS. ELDERKIN: I'll get the cite for you. It's in
- our expert testimony. And indeed other materials in this
- first group -- for example, polypropylene which is cited in
- the first group -- also comes in ultrahigh molecular weight
- form, and Arthrex's expert agrees that that material would be
- within the scope of the claim. And we'll get the cite for
- those.
- THE COURT: But apart from what Arthrex says, could
- you just point me to where in the specification you say is
- the novel and basic characteristics of the invention.
- MS. ELDERKIN: Sure. This is what I pointed to
- right at the beginning when I was talking about the --

Page 22 1 THE COURT: That's Column 2. MS. ELDERKIN: Column 2, Lines 49 to 62. You have 3 heterogeneous braids that exhibit a combination of 4 outstanding properties attributable to the specific 5 properties of the dissimilar fiber-forming materials which make up the braided yarns. You pick materials that have the properties you want, and you put them together in this particular construction, and you get a braided suture that 9 benefits from the properties of both of those materials. 10 that's at Column 2, Lines 49 to 62. And then there's also 11 discussion of that at Column 3, Lines 40 to 51, this concept 12 of mechanical blending. 13 And in answer to your question about where can you 14 find evidence with respect to the fact that these other 15 polymers, PVDF and PP, are also strong materials, that's in 16 Paragraph 37 of Dr. Brookstein's declaration. 17 THE COURT: So you're saying that the novel and 18 basic characteristics is the braiding of dissimilar yarns? 19 The braiding of dissimilar yarns --MS. ELDERKIN: 20 THE COURT: And that's all it is? 21 MS. ELDERKIN: -- in a way, in such a way that you 22 can achieve benefit of the properties, of the dissimilar 23 properties of the yarns. And that's because they are in 24 intertwining contact in the particular configuration recited 25 in these claims.

Page 23 1 THE COURT: In your view, so sometimes that will be 2 pliability and strength, and sometimes it won't? 3 Right, right, that's exactly it, and MS. ELDERKIN: 4 that Arthrex is improperly trying to -- first of all, is 5 misreading the spec, is overstating what the specification 6 says, and then is improperly trying to read aspects of 7 preferred embodiments into the claims. And what they say is --9 THE COURT: You know, that works for PE, but it 10 doesn't work so well for this because when you look at the 11 case law, I am supposed to go into the specifications to 12 understand the novel and basic characteristics. So it's not 13 reading in a limitation; it's actually understanding what's 14 novel about it. It's an odd analysis. It's different than a 15 normal claim construction. 16 MS. ELDERKIN: Yes, I agree. And what we're saying 17 is, if you read the specification, the general description of 18 the invention has nothing to do -- is not so specific. 19 just pliability and strength. It's the idea of mechanical 20 blending of discrete and disparate yarns with different 21 properties, and that Arthrex's reliance on this discussion of 22 pliability and strength is improperly focusing on discussion 23 of certain preferred embodiments and is too narrowly defining 24 the basic and novel characteristics of the invention. 25 And why do you add the limitation that THE COURT:

it can't be bioabsorbable? MS. ELDERKIN: We add that because it's also 3 important to look -- I agree with the case law -- as to why the "consisting essentially of" language was added to the 4 5 claims to begin with. And if I can get to that slide, the claims during prosecution were rejected at one point over 7 prior art that did disclose braided sutures. We argue they didn't disclose the braids of this type configuration. 9 examiner didn't agree with that. But the prior art, this 10 Kaplan and Doddi patents, disclosed sutures, but they had 11 bioabsorbable materials in the sutures. And to help avoid, 12 help to get around that prior art, we made the claim 13 amendment that's shown on the screen here. We added the 14 "consisting essentially of" language because otherwise it 15 was "comprising" language. And, as you know, "comprising" 16 means you could add anything under the sun to that claim 17 regardless of what it might do. So with the "comprising" 18 language, the claim would have been broad enough to include 19 bioabsorbable materials, and we were arguing our claim 20 doesn't include that. 21 THE COURT: And what does "bioabsorbable" mean? 22 MS. ELDERKIN: It means that once it's in the body, 23 it absorbs into the body. You don't have to, like, take the 24 stitches out later. They ultimately just absorb into the 25 body and disappear.

So we made this claim amendment where we added the

consisting essentially of language as well as the specific

- ³ recitation of the polymeric materials in response to the
- 4 rejection over Doddi and Kaplan. And when you look at the
- 5 amendment in which we did that, which is our Exhibit 3 to our
- 6 Markman brief, it couldn't be clearer that that's the case.
- We argued, the attorney argued, you know, this claim as
- 8 amended no longer claims bioabsorbable materials.
- 9 THE COURT: Because those patents had braided,
- bioabsorbable, discrete yarns? Is that what they had?
- MS. ELDERKIN: As I recall, they had discrete
- 12 yarns. They were not, as we argued, in direct intertwining
- contact as we claim here. We made that argument to the
- examiner. The examiner, for whatever reason, did not agree.
- We think he was wrong about that, but to proceed and to get
- the patent allowed, we then made this amendment to remove
- bioabsorbable materials, and then he withdrew the rejection
- over that prior art.
- So because the "consisting essentially of" language
- was so clearly added for the purpose of eliminating
- bioabsorbable materials, we say, "Well, that's a material and
- 22 basic characteristic of the invention too, bioabsorbable
- materials. You said that you're different from the prior art
- because you don't have bioabsorbable materials, so we say
- that that is a part of the basic and novel characteristics of

Page 26 the invention that it cannot include bioabsorbable materials." 3 THE COURT: All right, thank you very much. 4 you want me to do what now? You want me to -- you think it 5 sort of morphs into the same analysis because as soon as I adopt, if I adopt yours, you say, bang, there's an 7 infringement? Is that all there is to it? MS. ELDERKIN: Pretty much, your Honor. We have 9 obviously --10 THE COURT: And if I say, bang, no, this isn't it, 11 then they win? 12 MS. ELDERKIN: No. We say, bang, if you go for us, 13 we think there are no disputed issues of fact, and you should 14 grant summary judgment of infringement. But if you were to 15 find for them on either issue, there are genuine issues of 16 material fact about infringement that would preclude summary 17 judgment and would --18 THE COURT: Like what? You're talking about 19 equivalents? 20 MS. ELDERKIN: Yes. 21 THE COURT: So not to get ahead of ourselves --22 MS. ELDERKIN: I'm sorry. Not just equivalents, 23 but also under the "consisting essentially of," whether the 24 coating materially affects the basic and novel 25 characteristics. So even under their definition of what

- those basic and novel characteristics are, there's a fact
- issue under their definition of whether the coating
- 3 "materially affects" those basic and novel properties.
- THE COURT: Just getting to the coating for a
- minute, though, suppose I went with their view and there was
- evidence that the coating substantially improves the
- ⁷ handleability -- would that be it?
- MR. SABER: Handleability.
- 9 THE COURT: So you would say, at the very least,
- that gets a jury claim?
- MS. ELDERKIN: Yes, your Honor.
- THE COURT: So you would agree with their legal
- analysis, which is what I was actually struggling with a
- little bit, which is, if something like a coating materially
- improves on the invention, then that would qualify as taking
- you out of infringement?
- MS. ELDERKIN: I'm not sure that it would, your
- 18 Honor, and one of the reasons --
- THE COURT: As opposed to detracting or defeating
- the invention?
- MS. ELDERKIN: In this case, I'm not sure that it
- would because the patent even says you can put a coating on
- these sutures to enhance the pliability, to enhance the
- lubricity. I forget the exact term that they use.
- THE COURT: Right, I noticed that the coatings were

Page 28 mentioned, unlike some of the cases that we looked at where different sulfur contents or whatever. So I'm just trying to 3 understand the legal question. So suppose they acknowledge 4 coatings can improve flexibility, so you would say therefore 5 what, what legally? So that is part of the invention? 6 MS. ELDERKIN: Legally, is it a material change to 7 the basic and novel properties? A, you have a patent that says, hey, you can add a coating to these if you want to make 9 them more lubricious or slippery to enhance those properties, 10 if you want, so --11 THE COURT: So that makes it part of the invention, 12 the coating? 13 MS. ELDERKIN: Well, yes. Query: How would it 14 materially affect the basic and novel properties if the 15 patent says, hey, you can do this? And then there's also the 16 issue of fact about, A, of course, whether they've proven 17 that there is an improvement, but even if there is some 18 improvement, is it a material effect? 19 THE COURT: Well, their expert I assume says that, 20 right? 21 MS. ELDERKIN: Well, what their expert says is 22 that, when he was questioned at deposition, is, "Well, I can 23 tell an effect here, but it's subtle. And, you know, if I 24 were a surgeon and I actually had my gloves on, I don't know 25 if I'd be able to tell the difference."

Page 29 1 THE COURT: Does your expert say that it would not be a material improvement? 2 3 MS. ELDERKIN: Yes. THE COURT: All right, so what you're saying is, 5 give it to a jury. 6 MS. ELDERKIN: Right. 7 THE COURT: So that's where you would say it goes 8 from claim construction into an infringement fact analysis? MS. ELDERKIN: Right, if their construction of 9 10 "consisting essentially of" is adopted. 11 THE COURT: Thank you. 12 All right, you're up at bat. 13 MR. SABER: Thank you, your Honor. 14 THE COURT: You can give a stab at PE, even if you 15 think I'm wrong, but I'm just, as you know, as you can tell, 16 I'm struggling more with part two. 17 MR. SABER: I will, and I'm going to be short on 18 We also, of course, have a Powerpoint presentation. 19 THE COURT: That's why I love these cases. 20 MR. SABER: But I have a feeling we're probably not 21 going to look at very much of it today. Thank you. 22 THE COURT: Well, I had a chance to read the 23 It was really the appendices that I didn't get 24 through, so thank you. 25 (Discussion off the record.)

Page 30 1 MS. ELDERKIN: Your Honor, we have a number of 2 guests here. Would you have any objection if they sat in the 3 jury box where they could see the screens better? THE COURT: Oh, no, that would be fine. No vote, 5 though. You don't get a vote. 6 MS. ELDERKIN: Thank you. MR. SABER: I'll take a vote. If my guy gets veto 8 power, that would be fine. 9 THE COURT: It's like a jury, a hung jury. It's 10 all over. For those in the back row, you'll notice there's 11 like a tray table right next to the --12 MR. SABER: Well, your Honor, I gave it to you. 13 can tell you the slide numbers that we're on, and you've got 14 the paper version. 15 THE COURT: Sure. 16 (Discussion off the record.) 17 MR. SABER: Okay, thank you, your Honor. 18 THE COURT: It's show time. 19 MR. SABER: I think that was our seventh inning 20 stretch, a little bit early, though. 21 First, I want to thank Ms. Elderkin and her team. 22 The parties actually worked very hard together to try and 23 limit the claim construction issues, so we got it down to the 24 two that I think are the nub of the case.

25

THE COURT:

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I wish you all would stop being so

- friendly. It makes me think it's not a real patent case.
- But I appreciate it from all of you, as you know.
- MR. SABER: Well, I respect them, and I'm sure they
- 4 respect us, even though I know sometimes the papers can get a
- little nasty, but that's, I guess, the nature of our
- 6 business.
- THE COURT: Not compared to what I've seen.
- MR. SABER: I understand that your Honor is more
- 9 interested in the "consisting essentially of" issue, but if I
- 10 could just spend a couple of minutes --
- THE COURT: Sure, go ahead. This is your time to
- 12 do it.
- MR. SABER: My time. I want to start actually, and
- 14 I'm going to get to the nub of it, a bit on what the Phillips
- case did for claim construction because I think that this in
- many ways is the kind of case that they had in mind, because
- what the Phillips case said at its core is, you've got to
- look to the specification to understand the invention.
- They cited -- actually, I'm very proud -- they
- cited very enthusiastically to a case that I did, which is
- the Renishaw V. Marposs case, which stood for the proposition
- that the meaning that best fits what the specification was
- all about is usually the correct meaning. And that case has
- been cited a lot, and we were on the side that was advocating
- that position, so I guess perhaps that's why I passionately

- ¹ believe it.
- THE COURT: I know that since the Phillips case, I
- 3 saw some statistics that there have been more splits in claim
- 4 construction than there were before.
- MR. SABER: Your Honor, I haven't seen that, but
- 6 it's --
- 7 THE COURT: So rather than clarifying, I think
- 8 there's still a divide in the Federal Circuit.
- 9 MR. SABER: That statement doesn't surprise me,
- 10 knowing the Federal Circuit. But it is why we believe so
- strongly in our position, because we do believe that the
- whole notice function of claims will be served. But you have
- to understand what the term here "PE" would mean to someone
- of ordinary skill in the art reading this patent, and that's
- why we spent so much time on it, and we do believe that it's
- the appropriate analysis.
- 17 It's very interesting, the other side, the first
- thing they do is cite their expert for his opinion. Yet one
- of the very cases that they cite, the University of Florida
- case, calls expert opinion on the meaning of the claim the
- least favored type of extrinsic evidence and calls it
- extremely disfavored.
- THE COURT: The problem we run into is, I don't
- know what "polyethylene" means. I haven't had chemistry in
- many years. So at some level it has a chemical meaning in

- 1 the art, and it's not a defined term, and for me to
- ² understand it --
- MR. SABER: Right, you have to start somewhere.
- THE COURT: You have to start somewhere, so a
- dictionary makes sense, a technical dictionary.
- 6 MR. SABER: And, as I say, you know, despite the
- fact that we're accused of it, I think our papers were very
- 8 clear. We never said you can't look at the dictionary. We
- ⁹ just said you shouldn't start with the dictionary and then
- only look to the specification to see if there's a disavowal
- or something like that. That's exactly what Phillips said
- you shouldn't do. Phillips, I mean, said it, it's okay to
- look at a dictionary, and we said in our papers, it's okay to
- look at a dictionary. But what problem is in the fundamental
- difference of the approach of the two parties. They start
- with Dr. Hermes' opinion and the dictionary's and kind of end
- there. And I think Ms. Elderkin said it. She said, was
- there a disavowal in the specification? That's just simply
- not the analysis. The analysis is, to determine the ordinary
- meaning, you have to in every case look to the specification
- and the prosecution history, to the extent that that's
- relevant, to try and understand the notice that the patentee
- gave to the world as to what it means. And we think that
- when one does that, does that exercise that the Federal
- ²⁵ Circuit told us that we have to do, that the answer comes

- 1 screaming out to us. The specification --
- Sal, if you could go to Slide 10, I believe. This
- is where it starts to talk about what this patent is all
- 4 about. And I agree with Ms. Elderkin that it starts by
- talking about what was known and what was done, and it says,
- if fibers composed of highly lubricious polymers are used in
- ⁷ the traditional sense -- and she's right, they're talking
- 8 about what was known for these lubricious fibers -- then
- 9 you're going to get a highly pliable braid. And then it
- explains that in most instances, that highly pliable
- lubricious braid will be weak and unusable. And then the
- next sentence, which of course she didn't quote, really in
- many ways leaves no doubt. It says, "Hence, a trade-off
- between braid strength and pliability exists in the design of
- conventional braided multifilaments."
- It couldn't say it any clearer, your Honor, that
- you have to trade off. If you want it pliable, use these
- lubricious things that are pliable, you're going to have a
- strength problem. Or if you go with the strong ones, you're
- going to have a pliability problem. And that's the
- trade-off. That's the teaching that's given to us.
- I'm going to skip over the next one because that
- one really goes more to the "consisting essentially of," and
- if you could go to the next slide --
- THE COURT: Yes, that's what I was just going to

Page 35 Isn't that your big point on what's novel about this? MR. SABER: When we get to the "consisting 3 essentially of " --THE COURT: Isn't this it? This would be your 5 passage? 6 MR. SABER: The second passage, that's correct, 7 your Honor, the second passage. I was trying to just keep the two issues straight. I'll come back to this, if I may. 9 THE COURT: Exercising your strong points here, 10 that's true. 11 MR. SABER: Well, I think they're both strong 12 points. We wouldn't have moved if we didn't think that they 13 were. 14 And then we get to the description of the very 15 materials that are in the claim, and here again it's made 16 very, very clear what we're talking about. Now, Ms. Elderkin 17 likes to call this a preferred embodiment, and in many ways 18 this is a fundamental but, I think, very, very simple issue, 19 your Honor. This is not, as the claims came out, is not a 20 preferred embodiment. This is the claims. It's very, very 21 important to understand in the prosecution history of this 22 patent what happened. 23 THE COURT: So this is Column --24 MR. SABER: This is Column 4 starting at Line 9. 25 As Ethicon first filed this patent application, your Honor,

- 1 it had a very, very broad claim. All it required was -- I'm
- paraphrasing -- were two dissimilar yarns braided together in
- the direct intertwining contact. It didn't talk about any
- 4 specific materials. It didn't have the "consisting
- 5 essentially of "language either, but it was just two
- 6 different materials. That claim was rejected, and they
- ⁷ amended the claim.
- 8 And they did a couple things in the claim, and one
- of the things that's pertinent to the PE discussion is, they
- limited it to the specific materials, as you can see at the
- bottom of this passage, the seven materials that are listed
- starting with PTFE and going through PE and PP for the first
- yarn, and then for the second yarn it talks about the PET,
- 14 nylon and aramid. So this passage that we're looking at
- here, this isn't about a preferred embodiment. It's about
- the claims, and that's very, very critical to, we think, the
- answer to this question because these are the materials that
- are specifically identified in the claims.
- 19 THE COURT: Right.
- MR. SABER: And that's why we talk about them. And
- what does it say? It says that the first yarn is
- lubricious. It says that it's pliable. And then it says
- it's there to improve overall pliability, compliance, and
- surface lubricity. Then in the second paragraph it goes on
- to say that these lubricated yarns in the first set are

- mechanically blended with the yarns of the second set, which
- 2 act to provide improved strength to the heterogeneous braid.
- So there's no question what this patent is
- 4 teaching. It's teaching, it told us these lubricious yarns
- are too weak and you have the trade-off: Pliability, great,
- but you have braid strength is a problem. And here, they're
- saying, is the way we solved that problem: We took those
- 8 weak lubricious yarns, which were very pliable, and then we
- 9 had to add a yarn to it for braid strength.
- Now, I think the teaching is clear as a bell, and
- that's why, your Honor, when you look at those passages, we
- think that there's no question that to just take this term
- "PE" and blithely apply it to anything that has an ethylene
- molecule in it would just be so counter to what's being
- taught in this patent.
- It's very important, there's not a single word in
- this patent about this being a high-strength suture. It's
- quite the opposite. It says: We want to improve the
- handleability of the suture, we want to improve the
- pliability of the suture, and we don't want to hurt the
- strength too much. So this is the polar opposite of what
- ultra-high molecular weight PE is, which is, if not the
- strongest, one of the strongest substances --
- THE COURT: But you're essentially asking me to
- import extrinsic evidence into the claim construction.

Page 38 1 MR. SABER: I don't think so. I'm asking your 2 Honor to look at the passages that are in the patent. 3 THE COURT: No, because I don't know what 4 ultra-high molecular weight PE is. So you're basically 5 asking me to take your expert testimony as to what it is, and 6 to say it doesn't have characteristics, and therefore it 7 couldn't possibly fall generically within the concept of PE. MR. SABER: Well, actually, to look at it the way 9 your Honor says is, of course, that would be the infringement 10 question, is, what is ultra-high molecular weight PE, which 11 is one way to look at it. It would be an appropriate way to 12 look at it, I believe. 13 THE COURT: But as I'm understanding, polyethylene 14 can be all of these things. Almost undisputed, it can be all 15 of these things. And what you're saying is, but if you took 16 your kind, it wouldn't meet with this limitation in the 17 preferred embodiment. 18 MR. SABER: Again, let's talk about the evidence of 19 the case because I think that's always a great place to 20 start, and the only evidence that the defendants put in to 21 support the notion that PE can mean anything --22 THE COURT: Well, I mean, you have that --23 MR. SABER: Well, anything that has an ethylene 24 molecule, or polymer -- I'm not sure what word they used --25 is the two technical dictionaries. With respect to the

Page 39 second one, the expert admitted that he made an error, it didn't say it. And that happens, we all make mistakes. The 3 first one did say it, but the first one also says: Well, if you look at it as a source-based definition, yes, it's there, 5 but we don't think source-based definitions are the way to go, right in the same publication. And when I asked 7 Dr. Hermes about --THE COURT: What do you mean by "source-based"? MR. SABER: Source-based means it's just the 10 material that you start with, as opposed to molecular-based, 11 which is, what is it really, how is it really made? 12 THE COURT: And how many ends are there? 13 MR. SABER: Well, in this case, that would be it. 14 It could be other things too, but in this case, that's 15 right. And when I showed him what the authors of the very 16 thing they're relying upon said about this, he said, "I don't 17 have any information to disagree with the authors." That's 18 what he said. That's what Dr. Hermes said. So we're left 19 with very, very little. 20 THE COURT: Yes, but you're attacking theirs. What 21 do I have from yours? Do you have any dictionary, any 22 scientific treatise, or any expert who says that polyethylene 23 would not be understood to include the concept of ultra-high 24 molecular weight polyethylene? 25 MR. SABER: What we have is really the same

Page 40 1 evidence. THE COURT: You don't have anything different from 3 what they have? MR. SABER: No. I think that's what I just said. 5 Our expert did not offer a treatise that says the opposite of 6 what --7 THE COURT: So you're trying to have me import a 8 limitation from the specification and to limit polyethylene 9 to a certain kind of polyethylene? 10 MR. SABER: Well, I'm trying to understand what the 11 term "PE" when it's used in this patent, what --12 THE COURT: I understand your position, and I think 13 we need to move on because we still have the motion for 14 summary judgment left. 15 MR. SABER: Sure, sure. 16 THE COURT: So on "consisting essentially of," now, 17 let's say I took your passage. So then you would say that 18 coating did what? If I assumed you were right, which is what 19 I think is the hard issue in this, and, you know, whether 20 it's just any blending or whether it's a blending that 21 accomplishes certain purposes --22 MR. SABER: Right. 23 THE COURT: -- so then I've got your coating, and 24 the coating is specifically referred to in the specification. 25 That's correct. Could I go back to the MR. SABER:

Page 41 first question first? THE COURT: Sure. 3 MR. SABER: And I'll get to the coating issue 4 first. 5 THE COURT: Sure. 6 MR. SABER: The first step is, what are the basic 7 and novel characteristics? THE COURT: Right. MR. SABER: You know, the parties call it 10 "consisting essentially of." We actually all agree on what 11 the law of "consisting essentially of" is, that there's no 12 infringement if an unlisted material, which coating of course 13 is, if it materially affects the basic and novel 14 characteristics. 15 THE COURT: And you would say "materially affects" includes materially improves? 16 17 MR. SABER: Absolutely. And, I mean, I heard 18 Ms. Elderkin to agree with that, even though their papers say 19 the opposite. But I absolutely believe that that's correct, 20 and it was good to hear her say that today. 21 But the first step and where the parties do 22 disagree is, what are the basic and novel characteristics? 23 And, Sal, if we can go back to the slide before, the 24 paragraph that I told you I'd get back to, Slide 10, and this 25 paragraph that starts at 29: "In view of the deficiencies of

Page 42 the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handleability 3 characteristics." And then it goes on to say that "The fiber-forming materials contribute significantly to the 5 enhanced pliability without appreciably sacrificing its physical properties." Now, the dispute between the parties on whether to adopt this or the broader language that the other side 9 suggested really comes down to the same issue of the 10 amendment to the claim, because the law is one hundred 11 percent crystal clear that what you're looking for is the 12 basic and novel characteristics of the claimed invention, 13 which means you look to the language of the claims. 14 Once again, the amendment that I told you about I 15 believe answers this question one hundred percent. You 16 started with the broad claim that just had two dissimilar 17 The language that they read fairly went to just two 18 dissimilar fibers, but the claims at issue is to the seven 19 specific materials for the first yarn and the three specific 20 materials for the second yarn. And when you look at that, 21 then you get to the next slide again, and I won't go over 22 this in detail, but here it's talking about --23 THE COURT: And not bioabsorbable? 24 MR. SABER: I'll get to the -- bioabsorbable is

really a side issue that I don't think really has much --

Page 43 1 THE COURT: You don't have a problem with that, 2 right? 3 I don't have a problem with that. MR. SABER: THE COURT: All right, so we can add that in. 5 MR. SABER: You can add that in, that's fine. 6 That's not what this case is about. It's about this. 7 here when you're talking about the characteristics of the specific materials, again it's talking about handleability 9 and pliability characteristics that are improved. 10 you add the strength yarn so you're not appreciably hurting 11 the strength. 12 Again, I think the answer to here is very simple 13 and very straightforward: When you focus on the claim 14 language and you look to see what the specification says 15 about the language in the claims, it becomes clear that what 16 we offered is, we believe, the correct interpretation. 17 that's it. I mean, I think it's that simple. 18 Now, the coating issue, frankly, and what you talk 19 about in the patent, I don't think has any impact here on the 20 claim interpretation issue. I think it does have an impact 21 when we get to the infringement issue, but I'll answer your 22 question. 23 If we could go to the paragraph that has the I don't know if I have a slide on it. 24 coating.

Column 6. And there's several answers to the question, your

Page 44 It's at Column 6. It starts on Line 5. It says, "If desired, the surface of the heterogeneous braid can be coated 3 to further improve the handleability and knot tie-down performance of the braid." Then it goes on to talk about the 5 coating. 6 THE COURT: Now, which line are we at? MR. SABER: Line 5 at Column 6. This is the 8 paragraph where it talks about that you can add coating. So 9 that's the first sentence, and then if I can go further down 10 into the paragraph starting at Line 14, it says, "However, if 11 the surface of the heterogeneous braid is engineered to 12 possess a significant fraction of lubricious yarn system, the 13 conventional coating may be eliminated, saving expense as 14 well as avoiding the associated braid stiffening." 15 Well, there's three answers to your question. 16 First of all, legally -- legally -- the fact that the patent 17 says you can add something means nothing to the analysis of 18 whether it affects the basic and novel characteristics. 19 You've got to look to the patent to understand what they are, 20 and then you look to the evidence to see whether the unlisted 21 ingredient affects those basic and novel characteristics. 22 And we cited two cases in our brief which stood for that

fact the thing that was added, the thing the patent said you

proposition where, again, the patent says you can do this,

and nonetheless a court went through the analysis, does in

23

Page 45 could add? THE COURT: And those were trial court opinions, 3 right? MR. SABER: One was Federal Circuit, and one was 5 trial court, I believe. I believe that's right. I think one is in the Federal Circuit, and one is in the trial court. 7 You know, I sympathize with your frustration 8 because it's not like you're going to look at either one of 9 these cases and you're going to see a big bold holding that 10 says, even though the patent says you can add this material, 11 it could still affect the basic and novel characteristics. 12 It's not the way these cases are written. I know that. 13 when you look and see what happened in those cases, that's 14 exactly what happened. So the first answer is, legally, it 15 just doesn't matter. 16 THE COURT: So you're saying it has no legal 17 significance? 18 MR. SABER: That's right, it has no legal 19 significance. 20 Secondly, the prosecution history here is, again, 21 very relevant because as the claim originally was filed, it 22 was just a regular old "comprising" claim. If this were a 23 "comprising" claim, your Honor, we wouldn't have an argument 24 because if you added an additional ingredient on a 25 "comprising" claim, you still infringe. But once they did

- the amendment, and I think Mitek cited a case, if they're
- right, that said it automatically invokes the "materially
- ³ affects" analysis. And that's it.
- So you had language that was in the specification
- that might have described something before you added the term
- 6 "consisting essentially of," but once you added the term
- 7 "consisting essentially of," the question and the only
- question becomes, what are the basic and novel
- 9 characteristics of the claimed invention, and does the added
- ingredient affect those basic and novel characteristics?
- THE COURT: In which case it does not infringe?
- MR. SABER: In which case it does not infringe.
- THE COURT: Even though it facilitates, it doesn't
- 14 defeat?
- MR. SABER: That's right, and I think the law is
- pretty clear on that point too, and I heard Ms. Elderkin
- agree with that, that improving what the patent is all about
- also can affect the basic and novel characteristics.
- THE COURT: But what she would disagree with is
- that the coating really has that dramatic impact.
- MR. SABER: I understand that, and that, of course,
- is exactly the summary judgment question. It's not the claim
- 23 construction question.
- THE COURT: And she says, well, one expert says one
- thing, one expert says another.

Page 47 1 MR. SABER: Well, that's not correct, but I can 2 deal with that now, or I can deal with it later. 3 Sure, jump into it now. So if I accept THE COURT: 4 your theory as to what basic and novel is and I agree that 5 "materially affecting" includes improving on what you say is 6 the novelty here, she says that your expert says, yeah, the 7 coating substantially improves, what is it, pliability? MR. SABER: Right. 9 THE COURT: The ability to make knots, I guess. 10 And she says her expert says, no, it sort of has some more subtle effect. 11 12 MR. SABER: Well, let's look at what their expert 13 said, what the evidence is. 14 THE COURT: Which expert are we talking about? 15 MR. SABER: This is Dr. Brookstein who is the one 16 who gave testimony on this. Dr. Brookstein's analysis was 17 not what Ms. Elderkin said today. Dr. Brookstein's analysis 18 was, to affect the basic and novel characteristics of the 19 claimed invention means that you have to -- and I know it was 20 a little flowery language -- you have to miraculously change 21 it into something else or magically transform it so that it's 22 not offering the two things anymore. That's just not the law 23 and not right. That was his analysis, and that's what his 24 evidence went to principally. 25 The only other thing that he did, the entirety of

- Dr. Brookstein's evidence to try and show that there's no
- material affect on the coating was to say, he said, "Well,
- it's only 3.4 percent," which he called a small amount.
- Well, whether 3.4 percent is a small amount --
- THE COURT: What did 3.4 percent refer to?
- 6 MR. SABER: That the coating constitutes
- 3.4 percent of the volume of the suture, the weight of the
- 8 suture, and he says that's a small amount.
- 9 THE COURT: In terms of weight or in terms of
- improvement?
- MR. SABER: In terms of weight. He says the
- coating constitutes 3.4 percent of the weight. That's a
- number he got from us. He didn't do anything. That's
- correct. And he says, "Well, that's a small amount."
- THE COURT: So what did the coating do, decrease
- the lubricity?
- MR. SABER: The coating actually does several
- things. The principal things -- and, again, describing what
- coating does is a little bit like saying the world is round.
- Everyone in this business knows what coating does. That's
- why it's on a lot of sutures. I know you don't, and neither
- did I, your Honor. The principal thing it does is, it helps
- what's called "knot tie-down." Knot tie-down is the ability
- of the knot to slide down the suture.
- THE COURT: So it actually decreases lubricity?

Page 49 1 MR. SABER: No. It actually probably makes it more 2 lubricious because, you see, to back up --3 THE COURT: For knot tie-down, smoothness helps or 4 it --5 MR. SABER: Yes, it makes it more smooth. Here's 6 the problem --7 THE COURT: When I think of a nylon tie, sometimes 8 the smoother it is, the harder it is to tie. 9 MR. SABER: Well, the stiffer it is, the harder it 10 is to tie. 11 THE COURT: Well, both. Sometimes if there's 12 roughness, it can grab it. 13 MR. SABER: That's exactly right, and that's where 14 we're going. Braided sutures, just by definition, you think 15 about it, it's a braid. Think of a rope because it's much 16 bigger, it's easier to talk about it, right? A rope, right, 17 when it's braided, you know, there are bumps all over the 18 place, it's not smooth at all. Well, a braided suture is 19 much smaller, but the principle is exactly the same. It's 20 rough because it's a braid as opposed to the monofilaments 21 which are not a braid. 22 So what the coating does, the principal thing the 23 coating does is, it smooths out the rough spots. And by 24 smoothing out the rough spots, now when that surgeon makes 25 the knot, the knot will slide nicely down the suture. That's

- 1 the principal thing that coating does.
- Every witness in this case when asked, what does
- 3 coating do, lay witness, expert witness, they said, well,
- 4 it's for knot tie-down. It also makes it smoother. They all
- said that too. Pliability there's a little bit of a debate
- 6 about. That's why we didn't raise it in the papers. But as
- far as the handleability aspects of knot tie-down, no
- 8 dispute.
- 9 THE COURT: So you would say it improves
- 10 handleability?
- MR. SABER: Absolutely. It also improves
- pliability, but that's not raised by this motion. The
- handleability aspects, every witness, every witness agreed
- with it. We put in patent after patent after patent that
- said that. Ethicon patents, Ethicon is the largest suture
- company in the world, and all of their patents say that's why
- you have coating, every one of them that we found that talked
- about it, right? I showed those to Dr. Brookstein. He says,
- "I don't know. I don't know whether that's right. I don't
- know if that's not right. I don't have a background to do
- ²¹ that."
- That's why and one of the things we don't think
- he's qualified even to testify to this subject, but he
- couldn't agree or disagree when he was shown the very
- teachings. So it's one of those things, everyone knows that

Page 51 coating is there for that purpose. Frankly, this is a simple 2 case, your Honor. That's why coating is there. Everyone 3 knows that's why coating is there. All the evidence shows --THE COURT: Your expert says it anyway, right? 5 MR. SABER: Our expert says --6 THE COURT: So the expert -- I got some intuitive 7 feel from --MR. SABER: It's not just the expert, your Honor. 9 That's the point that I wanted to make. 10 THE COURT: Well, I don't know that, though. So 11 how do I know that a person of ordinary skill in the art 12 believes that coating improves handleability because it 13 facilitates knotting? 14 MR. SABER: Well, as I say, two reasons, and this 15 is a very important point: One is, our expert says it, as 16 your Honor said. Secondly, the evidence that he bases it on 17 is all this evidence that I just told you about. 18 Very interesting, when I asked Dr. Brookstein, do 19 you disagree with that, "I don't know." He never disagreed 20 with that. He never disagreed with that. You know, the man 21 never worked on coating of sutures, so when shown that, he 22 said, "I don't know." So his answer is, "I don't know." 23 That's not a material fact. So he doesn't disagree that --24 THE COURT: Well, the specification itself suggests 25 it.

- MR. SABER: Absolutely it does. I mean, that's how
- well known this thing is. And, again, that's why this case,
- frankly, in our opinion, never should have been filed because
- 4 "consisting essentially of" is a term of art. The basic and
- 5 novel characteristics I think are easy to define when one
- 6 understands it's the claims. And then the coating affects it
- is so universally known, that's why this case should end.
- But I do want to talk about what Dr. Brookstein
- 9 doesn't --
- THE COURT: So suppose there's consensus that it
- improves knot tie-down. How do I know it improves it a lot?
- MR. SABER: That's why everyone puts it on, your
- Honor. That's why everyone puts it on.
- THE COURT: I know, but I don't know that. I'm not
- a suture woman. So where does it say that it improves it
- 16 materially?
- MR. SABER: Well, that's why people get patents on
- it, your Honor. I mean, no one's going to use the word
- because that's a legal word. You've just got to look to what
- happens.
- THE COURT: No, but I understand, though. So your
- expert says it improves it substantially.
- MR. SABER: Well, it's a material effect.
- THE COURT: Right, fair enough. And the
- specification acknowledges it improves it.

Page 53 1 MR. SABER: That's correct. THE COURT: Their expert says what? 3 MR. SABER: Their expert doesn't disagree with 4 What their expert says is two things: One, he says 5 it's 3.4 percent, and that's a small amount. He doesn't say why. He says that's a small amount, 3.4 percent of the total 7 volume is a small amount. But he never says -- you know, whether something is small or big of course only has meaning, 9 you know, depending upon what you need. The evidence in the 10 case, the evidence --11 THE COURT: In other words, 3.4 percent is your 12 product? 13 MR. SABER: That's correct, that's correct, because 14 now we are getting into the infringement aspect. 15 THE COURT: So he's saying that amount of coating 16 wouldn't improve it a lot. 17 That's what he says. Well, no, he MR. SABER: 18 doesn't say that. He just says it's a small amount. 19 doesn't say why that's relevant or not. He just says it's a 20 small amount. 21 The evidence in the case, the evidence is that much 22 less than that, and one of the patents of the two patents, 23 one of them it's, I think, .01 to .1 percent is what's needed 24 to get the handleability improvements. The other one --25 THE COURT: That's your patent?

Page 54 1 MR. SABER: No, that's not our patent. These are 2 patents in the field teaching what it is about coating, how 3 much coating you need. The other one I think is .02 to .2 percent. This is 3.4 percent. There's absolutely no 5 basis, no basis at all for his testimony that 3.4 percent is 6 a small amount. He says it, but he never shows about it. 7 There's a burden of proof issue here, your Honor. 8 They're the plaintiffs in this case, and once the issues of 9 material effect are shown, it's their burden to show, to come 10 forward with evidence that it doesn't have a material effect. 11 THE COURT: Good, I understand your position. 12 me jump back to her on this. Then hopefully we'll get to 13 unethical conduct. 14 I need you to -- first of all, I find it, as you 15 can tell from my comments, a difficult issue about what's the 16 novel and basic. I think both sides have a good argument, 17 and there's a strong argument for Arthrex on this as well. 18 If I went with that argument, you said, well, if I go with 19 that, you've got evidence that the coating doesn't materially 20 improve it. 21 Exactly, your Honor. MS. ELDERKIN: 22 THE COURT: And could you read me -- do you have 23 Do you have it somewhere? Because this is the piece I'm 24 weakest on because I just got all the documents yesterday, 25 so --

Page 55 1 MS. ELDERKIN: Sure. It actually is out of their 2 own expert. They had a surgeon, Dr. Burks, look at a suture 3 that purportedly was coated and then purportedly not coated. 4 And there's a whole other issue there, but let's assume for 5 the sake of today that the suture that Dr. Burks looked at, one was the coated suture and one was the same suture without 7 the coating, and he looked at it to see if he could tell the difference in its handleability and the ability to tie a 9 And he looked at it, and in the cases where he looked 10 at it, he was able to tell the difference. But when he was 11 asked, "Okay, well, tell me about that difference --" and 12 this is Dr. Burks' testimony. It's Mitek Exhibit 9. It's on 13 our Slide 34. 14 THE COURT: Let me just go with you. 15 MS. ELDERKIN: Sure. 16 THE COURT: And you say this is their guy? 17 MS. ELDERKIN: It's their guy on whom they rely for 18 this argument that there's a material difference. 19 able to tell the two apart, but we asked him, "Well, how 20 would you characterize the difference between the sutures?" 21 And he said, "Well, the difference, I think, is subtle, and 22 there's no doubt in my mind that I could line up, you know, a 23 hundred sutures and have error where I would say, you know, I 24 think this one is one way or the other and make a mistake. 25 So there's certainly not enough difference to clearly say

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 m 1}$ that I know every time exactly how that feels."
- And then he also admitted that he was doing these
- tests with bare hands. He said he didn't do the tests with
- 4 his surgical gloves on. He said, "I can't tell you, if I had
- my gloves on, if I'd be able to tell the difference between
- 6 these sutures or not."
- 7 THE COURT: So are you basically conceding that it
- improves the tieability but just not by a lot?
- 9 MS. ELDERKIN: I'm conceding that a coating on a
- suture of this particular type can improve the
- handleability. It's not material here. And I do want to
- correct the record. If the impression was left that I said
- that even in a material improvement here in pliability or in
- handleability would remove the FiberWire from the claims
- under the "consisting essentially of" language, that's not
- what I intended.
- The reason for that is -- well, two reasons. First
- of all, as Mr. Saber said, everybody coats sutures. Now,
- there are a lot of different coatings. They're not all
- silicone coatings like here. Everybody coats sutures. Why
- on earth would Mitek put an amendment in its claim that's
- going to remove all sutures because they're all coated,
- ²³ number one?
- And, number two, where the patent itself says
- optionally you can coat this if you want, and maybe that will

- enhance your handleability a little bit more, so that can't
- 2 be a major or material change in the basic and novel
- properties of this invention if the patent says: It's
- 4 optional. Do it if you want. Do it if you don't want.
- So the evidence either way, under either of the
- 6 parties' --
- THE COURT: Do you have any case law that might
- 8 discuss this where it's an option in the specification but
- 9 it's not included within the terms of the claim, how I would
- understand? Because I'm having trouble legally with what to
- do with it, where it's plainly disclosed. In fact, it says
- that there's some improvement that comes from coating, so
- wouldn't --
- MS. ELDERKIN: Right, my colleagues here are
- scurrying.
- THE COURT: I'm sort of struggling with whether or
- not that affects my analysis.
- MS. ELDERKIN: This is a very old case we cited in
- one of our briefs. It's the ex parte Boukidis case,
- B-o-u-k-i-d-i-s. It's at 154 USPQ, 444. It's old, and it's
- from the Board of Appeals. It's 1967. But the Board there
- did say that "Consisting essentially of does not necessarily
- limit claims to exclude other things when the specification
- clearly indicates that the other constituents may be present
- as well." Other than that, I agree, your Honor, there's not

Page 59 of 89 Page 58 a lot of jurisprudence on it. THE COURT: Chisum doesn't speak about it? 3 anyone looked at the treatise on patents? MS. ELDERKIN: I don't believe so. 5 THE COURT: It's just one of the areas I haven't 6 had a chance to address in particular terms. All right, 7 well, thank you. Now, did you want to address anything else before 9 we moved on to inequitable conduct? 10 MS. ELDERKIN: I think unless your Honor has any 11 questions --12 THE COURT: Do you want to respond? So Burks says 13 it's subtle. 14 MR. SABER: Well, if I could just respond, first of 15 all, to give you some case cites because we do cite cases for 16 the proposition that whether it's in the patent or not, you 17 can still affect the basic and novel characteristics. 18 THE COURT: And is that already in your brief? 19 MR. SABER: It is, your Honor. 20 THE COURT: Okay, and the cases are? 21 MR. SABER: It's the AFG case and the 22 American Machine case, and they are cited in our brief. 23 I just will notice that what Ms. Elderkin said, even the one

that she cited says, "Well, not necessarily." And that's

right, of course it's not necessarily. You just have to do

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Page 60 of 89 Page 59 the analysis. Good. Thank you. THE COURT: MR. SABER: With respect to Dr. Burks, first of 4 all, Dr. Burks was just brought in to do one limited test. 5 That's all it was. He wasn't the expert to speak about all the evidence of what coating does. So they just ignore all the evidence of that on Dr. Burks. And it's very interesting, they leave out -- well, Ms. Elderkin did cite 9 where he said, "If I got a hundred, I might get it wrong." 10 That's right, if you got a hundred, you might get it wrong. 11 But what did happen is -- you know, they tried at the 12 deposition, because he had done it for his report, and, of 13 course, he got those right, they said, "Well, we're going to 14 trick him. We'll make him do it at the deposition again." 15 Guess what, he got them all right. That doesn't establish a 16 genuine material fact. 17 Also, the law is, your Honor --18 THE COURT: But he did use the word "subtle." 19 MR. SABER: He did, he did. And, you know, these 20 are differences that of course they're not -- these are 21 things that make things better, and it's important -- the 22 reason why many, many people coat sutures is precisely

cited to your Honor in the case law, and he's very, very

because it's what the marketplace wants. It's of importance

to the marketplace. That's the test of materiality, as we

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- 1 consistent with that.
- The other thing too is that the law is -- again,
- this is on summary judgment -- they cannot create a material
- 4 fact simply by criticizing our evidence. This is our
- ⁵ evidence. They have to come forward with their own, and they
- 6 haven't done it, your Honor.
- THE COURT: Well, I don't know if that's true. If
- you yourself have two competing sets of statements, I don't
- 9 know that they couldn't rely on that.
- MR. SABER: Well, as I say, you know, the law does
- say they're the ones that have to come forward with
- 12 affirmative evidence.
- THE COURT: Yes, they're coming forward first.
- MR. SABER: Right. And, as I say --
- THE COURT: Okay, I mean, does your expert address
- this at all? You said it did in your other case.
- MR. SABER: I'm sorry?
- THE COURT: Does Brookstein?
- MS. ELDERKIN: Yes, Brookstein does address it. He
- didn't do his own test, but he does address the whole --
- THE COURT: Does he really have a miracle
- 22 standard?
- MS. ELDERKIN: No, not at all, your Honor.
- MR. SABER: It's what he testified to. You know, I
- asked him what he meant, and that's what he said, that's what

- it is. So what we're left with is Dr. Burks who got it
- 2 right, and we have all the evidence of what coating does.
- 3 That's the --
- THE COURT: Okay, thank you. All right, so what's
- 5 the issue on inequitable conduct?
- MS. ELDERKIN: Mr. Bonella will address this for
- your Honor.
- MR. BONELLA: Your Honor, Mitek moved for summary
- ⁹ judgment of no inequitable conduct, to dismiss Arthrex's
- defenses of inequitable conduct, and that motion should be
- granted for several reasons. First, Arthrex's allegations
- are based on an incorrect, overruled legal standard. Second,
- the references that we're talking about here were not
- withheld from the Patent Office, your Honor. In fact, they
- were the subject of prosecution. Third, Arthrex cannot show
- a misrepresentation, and, fourth, they cannot show the
- threshold level of intent to deceive by clear and convincing
- 18 evidence.
- Your Honor I'm sure knows there are two prongs
- essentially to the inequitable conduct analysis --
- THE COURT: What page are you on?
- MR. BONELLA: Slide 37, your Honor. Do you have
- ²³ it?
- There's two prongs to the inequitable conduct
- analysis. First is whether there was a material omission, a

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 m l}$ withholding, or a material misrepresentation, or, secondly,
- whether there was intent to deceive. Arthrex cannot show
- either with respect to either of those two allegations.
- First, let's talk about the proper standard.
- 5 Arthrex's inequitable conduct defense should be dismissed on
- summary judgment because it's become clear in their response
- papers that they're relying on an incorrect legal standard.
- 8 Arthrex on Page 10 of its brief cites to --
- 9 THE COURT: So just remind me. What was the basic
- claim of inequitable conduct, failure to disclose
- 11 references? Was that it?
- MR. BONELLA: No, it's not, your Honor. That's not
- it at all, and that's the interesting point. This wasn't
- about failure to disclose. In fact it's about the references
- that were the very subject of the office actions and
- prosecutions in front of the Patent Office.
- 17 Arthrex makes two allegations. First, they say
- there was a reference, the the Kaplan reference. And they
- say the claims were rejected over the Kaplan reference, and
- the patent attorney came back and tried to distinguish the
- 21 Kaplan reference. Again the claims were rejected over the
- 22 Kaplan reference, and the patent attorney came back and he
- distinguished the claims as a result by adding the
- "consisting essentially of" language to remove bioabsorbable
- ²⁵ materials.

1 Arthrex disagrees with the interpretation of the

reference that the prosecuting attorney took. During the

prosecution, the prosecuting attorney said the sheath in the

Kaplan patent was a semiabsorable or fully absorbable

5 sheath. And what we're claiming here by adding the

graphs of the string essentially of language is, that we're claiming

a nonabsorbable sheath, and the Patent Office ultimately

agreed with that position and allowed the patent.

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What Arthrex is saying is, that interpretation of
the patent Arthrex disagrees with. They say, "The patent
attorney got it wrong, and because he got it wrong, he
committed inequitable conduct." That's essentially the
argument.

The second allegation they have is about another
reference that was the subject of prosecution. This
reference is the Burgess reference. The claims were
initially rejected over the Burgess reference. The Burgess
reference is the European patent application. It's a page
and a half long with no drawings, and it's about fishing
line.

In responding to that rejection, the patent attorney came back and said, "That's about fishing line, not about suture. Fishing line is not analogous art, and because it's not analogous art, it's not within the circle of art that you look to in determining the validity and the

- obviousness analysis, and made statements about why fishing
- line and the Burgess reference were not analogous art.
- 3 Arthrex argues those statements were misrepresentations.
- So this isn't about withholding references. In
- fact, the Burgess reference was disclosed early on in
- 6 prosecution by the prosecuting attorney, and now he's being
- accused of thinking inequitable conduct with respect to the
- 8 very reference he disclosed. So it's not your typical case
- 9 where there's --
- THE COURT: More of a misdescription or --
- MR. BONELLA: That's what they're trying to allege,
- your Honor, yes.
- THE COURT: All right, thank you. Did want to
- 14 finish up?
- MR. BONELLA: Yes, I have more.
- THE COURT: All right.
- MR. BONELLA: Okay. They say -- we look in their
- briefs, and say, well, what -- we submitted our motion, and
- what did they say in response? They said, Arthrex's argument
- was, we're relying on a gross negligence standard, citing to
- 21 Reactive Metals and Alloys V. ESM from the Federal Circuit in
- 1985. Page 10 of Arthrex's brief says, "Gross negligence may
- constitute sufficient wrongful intent to support a holding of
- inequitable conduct." But that is just wrong. That case was
- overruled by Kingsdown in 1988. And lest there be any doubt,

- in 2003 in the Ulead case, the Federal Circuit said,
- specifically referring to this Reactive Metals case that
- 3 Arthrex relies on, said, "To the extent that Reactive
- 4 suggested that a finding of gross negligence standing alone
- is sufficient to satisfy the intent prong of inequitable
- 6 conduct, has been overruled." That standard is just wrong.
- 7 They're relying on the wrong standard. Their allegations
- 8 fail as a matter of law.
- 9 But even if we look to what Arthrex is alleging
- about Kaplan, they say, well, there was a misrepresentation.
- Arthrex's litigation counsel disagrees with the prosecuting
- 12 attorney's interpretation of the reference. Well, what
- evidence is there that there was a misrepresentation based on
- 14 Kaplan? We have no testimony from Arthrex's technical
- experts about Kaplan. They didn't ask him to opine about
- 16 Kaplan. No testimony from their technical expert.
- Arthrex's patent law expert, he likewise was not
- asked to testify about Kaplan and did not provide any
- opinions about Kaplan. Telling.
- The only evidence we have is Arthrex's litigation
- counsel's interpretation of Kaplan in its briefs, but
- 22 Arthrex's litigation counsel is not one of ordinary skill in
- the art who is able to construe a technical reference and
- explain what it means. So Arthrex lacks the requisite
- evidence to even show a material misrepresentation with

Page 66 respect to Kaplan. And the Akzo case from the Federal Circuit is right 3 on point here. THE COURT: Well, I don't need to go through all. 5 Let me ask you this: So I don't need to address this, right, 6 if I find there's no infringement? 7 MR. BONELLA: If you find that there's no 8 infringement as a matter of law, then --9 THE COURT: So this only comes up -- you would only 10 need a ruling if I find there's an infringement because then 11 you don't want to be thrown out on some sort of inequitable 12 conduct? 13 MR. BONELLA: Right, if there's infringement or if 14 there is going to be a trial, if there's dispute of fact. 15 THE COURT: Well, it goes to me anyway, right? 16 MS. ELDERKIN: Yes. 17 THE COURT: This usually isn't sent to a jury, 18 right? 19 MR. BONELLA: Inequitable conduct is for you, 20 that's correct. It's purely an issue of law. 21 THE COURT: Why do I have to do this? 22 MR. BONELLA: Why do we have to do it? 23 the work for trial, we know our witnesses, we know how to 24 prepare everything. 25 THE COURT: Well, this isn't going to go to a jury

- trial anyway. So what you really need right now is a ruling
- on claim construction, right?
- MR. BONELLA: That's correct, your Honor.
- THE COURT: So that's what you need right away.
- 5 This can go on a slower boat.
- 6 MR. BONELLA: That's correct, your Honor.
- THE COURT: I understand why it's important because
- 8 no one likes to be just hanging out there.
- 9 MR. BONELLA: That's correct.
- THE COURT: So what you really need right now is a
- decision because then we'd make a decision as to whether we
- go to trial on infringement/validity. This is a "me" issue
- later on, right?
- MR. BONELLA: That's correct.
- THE COURT: Okay, this won't go to a jury under any
- theory, as I understand it.
- MR. BONELLA: That's Mitek's position.
- THE COURT: Is that right? It's still the law,
- 19 right?
- MR. SABER: That's right. It's an equitable issue,
- so it can go to the jury, but your Honor can do it too.
- THE COURT: Okay, good, thank you very much. So
- why are trying to -- they say every patent case now, you
- can't have one without a claim of inequitable conduct.
- MR. SABER: Right. Your Honor, I wouldn't blame

- 1 him for citing that law. I cite that law when I'm on the
- other side. And if I thought that this was just a case like
- that, we wouldn't have filed it. That's the bottom line.
- I just want to address a few things Mr. Bonella has
- said. I'm not going to give a long argument on here. First
- of all, on this wrong standard thing, it's an oversell if
- ⁷ I've ever heard it. Should we have cited that case?
- Probably not. What has happened is that on the knowledge
- thing, the test really is, you don't have to show actual
- 10 knowledge; you can show that they knew or should have known.
- THE COURT: Yes, the reckless disregard kind of
- 12 standard.
- MR. SABER: Well, you have to have an intent to
- deceive, but you can show the intent to deceive by showing
- that they knew what they did was wrong or they should have
- known what they did was wrong.
- THE COURT: But it is more or a recklessness or a
- willful blindness kind of thing rather than a negligence.
- MR. SABER: Yes, but, you know, we probably
- shouldn't have used the word "gross negligence." It was just
- an alternative theory on the intent piece.
- THE COURT: All right, we're getting out of it,
- right? Let's get to the merits.
- MR. SABER: That's all it was.
- Mr. Bonella is correct that this was not a

withholding of the reference case. But it's not, and particularly with respect to the Burgess reference, it was 3 not a question of just fighting about what the reference That's not the inequitable conduct that's alleged. 5 See, Burgess was a fishing line, a braided fishing line of ultra-high molecular weight PE and polyester and nylon, the 7 same thing that their claim is, if one were to conclude that PE falls within the claim. And Mr. Bonella is correct that 9 there was an issue of not analogous art there, but that's not 10 all they said. What they said is, they talked about -- what 11 the attorney did is, the attorney talked about that 12 combination, the Burgess combination of ultra-high molecular 13 weight PE and polyester and nylon and what it would be. And 14 in describing what it would be as a braid for a suture, 15 that's the misrepresentation; not about what Burgess teaches 16 but what that braid would work as a suture. And he said two 17 very important things: He said it would make a bad suture. 18 It would make a bad suture, particularly because it has 19 ultra-high molecular weight polyethylene in it, which has low 20 stretchability and minimal elongation -- I might have got 21 that backwards -- right, and it would be terrible material to 22 use for a suture. By the way, part of the record and part of 23 the reason why PE shouldn't be construed to include 24 ultra-high molecular weight PE, the thing that they told the 25 world would work poorly for a suture, but here it is, they

- said it would work poorly for a suture, it would have bad
- 2 knotting characteristics if you used it for a suture. And
- then they said -- here was the punch line -- even if one
- 4 looked to the teachings of the fishing line art -- and, of
- 5 course, what was the teaching of the fishing line art that
- 6 was there, Burgess, right? -- if a suture designer looked
- there, one would inevitably design an unacceptable suture.
- 8 Those were the statements that Ethicon made to get over this
- ⁹ rejection, and they got over this rejection.
- THE COURT: But why would you even look at Burgess
- if it was a fishing line?
- MR. SABER: Because it is the same kind of thing.
- 13 It's the same thing, and you always do this in patent law.
- You look at analogous things. Like, for instance, they
- talked about Kaplan. Kaplan wasn't a suture, by the way. It
- was a prosthesis, and they looked to it because it was close.
- THE COURT: What does that mean?
- MR. SABER: That's an artificial --
- THE COURT: Like a leg?
- MR. SABER: Yes, it is. It's not a leg in that
- case, but that's what it could be.
- THE COURT: Well, why would that be anything like
- ²³ a --
- MR. SABER: A suture?
- THE COURT: Yes.

- MR. SABER: Because it's the same kind of problems
- that you're trying to do, where people would look.
- THE COURT: For the whole leg or --
- MR. SABER: First of all, it wasn't a whole leg.
- 5 It was an internal piece like a ligament. It's an artificial
- 6 ligament, I think is what it was in that case. And that's
- why you always are looking to these other areas all the
- 8 time. There's nothing unusual about that at all and --
- 9 because the question is, would you look there --
- THE COURT: But these are the gray areas as to
- whether you'd look to --
- MR. SABER: Excuse me?
- THE COURT: These are somewhat gray areas. I get
- into these fights all the time whether something should be
- considered prior art or not.
- MR. SABER: Well, this is not a question of whether
- it's prior art. It is.
- THE COURT: But why would you ever need to knot or
- have handleability on a fishing line?
- MR. SABER: Well, because you do have very, very
- similar kinds of things.
- THE COURT: You just tie it onto a hook and throw
- in the line, says a non-fisherwoman. But, I mean, it's not
- the same kind of thing.
- MR. SABER: It's not exactly the same, of course

- $^{
 m 1}$ not. In fact, Pearsalls is the company that makes the
- suture. They make the fishing line too, not this fishing
- line, but they make fishing line out of this product too. I
- 4 mean, it's what people in the industry do, and that's where
- you get your ideas about as to what to do, and that's why it
- was cited against them by the examiner. And what they said
- is, if you did that, you'd get a bad suture. So it isn't a
- 8 fight about what Burgess says. The fight is, they said you'd
- ⁹ get a bad suture if you made it out of this material. If you
- looked to the fishing line art, if you looked to the Burgess
- braid, it would be a bad suture.
- Here's where the inequitable conduct comes in. We
- took Dr. Steckel, one of the inventor's, testimony, and I
- asked him, "Well, if you did this combination, did you
- think -- "this is when he was doing his invention -- "did you
- think you'd get a good suture or a bad suture?" He fought
- me, he fought me, he fought me, but finally he said, "Yeah,
- we thought it was a good idea. You'd get a good suture with
- ultra-high molecular weight PE and polyester, " or PET I think
- is what we were talking about but the same thing, the exact
- opposite of what was said by Ethicon's attorneys to the
- Patent Office. They said it would be a bad suture. They
- said it would have bad knot characteristics.
- Dr. Steckel said, "Mr. Hunter and I, the other
- co-inventor, we thought it would have good knot-tying

- abilities. We thought it would make a fine suture, all
- 2 right? They didn't disclose that to the patent office. They
- said, "No, no, no, if you followed these teachings, you'd
- 4 have a bad suture," without ever knowing that their inventors
- allegedly, because this is what he testified to, said, "We
- 6 think the opposite." That's inequitable conduct. That's not
- right, and that's what you shouldn't do, and that's why there
- was a material misrepresentation here.
- 9 THE COURT: All right, so how do you respond to
- 10 that?
- MR. BONELLA: If I may, your Honor?
- THE COURT: So your inventors, do they think you
- could borrow from the fishing technology and make a good
- suture?
- MR. BONELLA: Absolutely not. I heard a lot of
- talk up here, but I didn't see any evidence. And if we look
- at the evidence, what does the evidence really show? These
- are the three statements, your Honor, that Arthrex points to
- in their brief. There's a lot of talk up here about this
- material and that material and what people thought about
- certain materials, but the three statements Arthrex says in
- their brief that were misrepresentations, number one, "The
- fishing line of Burgess would have poor knot strength and
- security properties." Number two, "The property requirements
- for fishing line yield a braid with poor knot strength and

- security." Number three, "Even if a medical designer did use
- 2 the teachings of the fishing line art to modify a suture,
- then he would inevitably design an unacceptable suture."
- 4 All the three statements they actually point to,
- the evidence in the record, are about fishing line or
- 6 Burgess. So the question is, did Dr. Steckel say anything
- inconsistent with those statements? Because what they're
- 8 trying to set up is that the inventor knew something that was
- ⁹ inconsistent with this.
- THE COURT: He says that it did. He said it would
- 11 make a fine suture.
- MR. BONELLA: That's right. Are any of these about
- suture? No. The one statement is about a fishing line of
- Burgess, the second statement is about the property
- requirements for fishing line, and the third statement is
- what a medical designer would do if faced with the fishing
- line art. Dr. Steckel did not testify about fishing line.
- Dr. Steckel did not testify about the fishing line
- properties. He didn't testify about what a suture designer
- would do when faced with fishing line, and he didn't testify
- about the teachings of Burgess.
- If you look at the undisputed evidence, your Honor,
- Mitek Fact No. 116: There is no evidence that Dr. Steckel
- was familiar with fishing line properties, undisputed. Mitek
- Fact 117: There's no evidence that Dr. Steckel considered

- designing sutures from fishing lines, undisputed. So the
- 2 actual statements that they're looking at, there's no
- 3 statements from Dr. Steckel that are inconsistent.
- What Dr. Steckel did say was that he believed
- 5 braiding ultra-high molecular weight polyethylene with PET
- 6 would make an acceptable suture, not a fishing line, a
- ⁷ suture. And the Burgess reference Mr. Saber says is the same
- 8 braid. There's no evidence in the record about this. He
- 9 does all these things about what fishing line --
- THE COURT: So you're saying that Steckel said in
- the abstract, that those two braided together would be fine,
- but wasn't looking at the Burgess patent?
- MR. BONELLA: I'm sorry, I didn't understand your
- question, your Honor.
- THE COURT: You're saying that when he was
- responding -- do you have the exact Q and A that's being
- relied on? Is it in the record?
- MR. BONELLA: The exact Q and A, if you want to
- look at the exact Q and A from Dr. Steckel that they rely on,
- it's on Page 2, Slide 48 of our brief, that he believes that
- would make an acceptable suture. He didn't testify anything
- about fishing line, fishing line properties, or the teachings
- of Burgess, or what one of skill in the art would do based on
- fishing line art. He said, "I would design the sutures, and
- I thought these would make acceptable sutures. Sutures are

Page 76 sterilized --" THE COURT: Wait, wait, you're going too fast. 3 Where? 4 MR. BONELLA: I'm sorry, Slide 48. This is the 5 only testimony that they cite from Dr. Steckel, Pages 179 to 6 180. 7 THE COURT: All right it's just a little pale 8 because it's yellowed over. I'm having trouble reading it. 9 "We had a belief that it could lead to --" 10 MR. BONELLA: " -- an acceptable suture." 11 THE COURT: What was the "it"? 12 MR. BONELLA: The "it" is a braid of direct 13 intertwining contact of ultra-high molecular weight 14 polyethylene and PET. And so he believed that that would 15 make an acceptable suture, but that's in no way inconsistent 16 with anything that was said to the Patent Office. 17 THE COURT: Just help me. "Did you have -- in 18 formulating this idea, did you have any sort of belief that 19 if you put -- " what, Dyneema? 20 MR. BONELLA: Dyneema is a trade name for 21 ultra-high molecular weight polyethylene. 22 THE COURT: Okay, "-- with PET --" 23 MR. BONELLA: Yes. 24 THE COURT: And that's what you have in your second 25 set of filaments, right?

Page 77 1 MR. BONELLA: Correct, your Honor. THE COURT: " -- It would lead to an acceptable 3 suture?" MR. BONELLA: Right, which is what he thought he 5 disclosed in the patent, polyethylene PET. 6 THE COURT: What's Ethibond? MR. BONELLA: Ethibond is an Ethicon suture. 8 a polyester braided suture in direct intertwining contact. 9 It's a product that's been around for many years. 10 So Dr. Steckel, all he was saying was, "I thought 11 it would make an acceptable suture." He's not saying 12 anything about fishing line, fishing line properties, what a 13 medical designer would do based on fishing line. 14 statement is in no way inconsistent with any of the three 15 statements they actually identified from the record. 16 And we disagree about what Burgess discloses, but I 17 don't think we even need to go there because there's no 18 inconsistency based on the evidence they cited. And if you 19 look to try to find the evidence they cite from Dr. Steckel, 20 it's not even in their argument. It's on Page 2 of their 21 brief, and you kind of have to infer this is what they're 22 relying on. But Burgess discloses a fishing line. It says 23 there's a braided construction, but it doesn't say what type 24 of braided construction. It just says braided construction. 25 It's a page and a half long, double-spaced, no drawings.

Page 78 1 THE COURT: Okay, I've got the gist of the 2 problem. Thank you very much. 3 MR. SABER: Your Honor, could I just briefly 4 respond, just very, very briefly? 5 THE COURT: Yes. 6 MR. SABER: I can't say this one sentence any more clearly: What Dr. Steckel said is that the Dyneema and 7 polyester together he thought would make an acceptable 9 What Ethicon said, that if you look to that 10 combination, you would inevitably design an unacceptable 11 suture. They're the exact opposite. 12 THE COURT: Where does it say that? 13 MR. SABER: I'm looking -- the easiest place is, 14 I'm looking in Mitek's Powerpoint Slide 45. It's an accurate 15 "Even if a medical designer did use the teachings of 16 the fishing line art to modify a suture, then he would 17 inevitably design an unacceptable suture." 18 You can't get any more opposite than that. 19 THE COURT: What's that quote from? 20 MR. SABER: That's from the response that Ethicon 21 filed in the Patent Office. They said you would inevitably 22 design an unacceptable suture. Dr. Steckel, the inventor, at 23 the time believed, with that same combination, you would 24 design an acceptable suture, the exact opposite. And that's 25 why we have an inequitable conduct allegation here.

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               MR. BONELLA: If I could just respond quickly?
               THE COURT: Do we know whether the braiding is the
 3
     same?
               MR. SABER:
                           It has to be. It says -- the
 5
     Burgess -- the Burgess they never -- the reason Burgess was
 6
     cited is that it was a braid of -- it's called Dyneema in the
 7
     claim, in the Burgess reference, which is ultra-high, as
     Mr. Bonella correctly said. It's polyester and nylon and --
 9
               THE COURT: Polyester is PET?
10
               MR. SABER: Polyester, PET, the same thing.
11
               THE COURT: Okay.
12
               MR. SABER: Polyester or nylon together braided
13
                   It's a fishing line braided together. That's
     with Dyneema.
14
     what it says. There's no other thing other than a braid.
                                                                 Ι
15
     mean, that's what a braid is.
16
               You know, Ms. Elderkin tried to talk about this
17
     core thing. There's no core in Burgess. There's no talk
18
     about it. It just says a braid of these two materials.
19
     That's it. And, of course, that's what we're talking about.
20
               THE COURT: Do we know from looking at Burgess
21
     whether it's the same kind of braid?
22
               MR. SABER: There is only one kind of braid.
23
     you're braiding it together, if the two materials are braided
24
     together, they're braided together. I mean --
25
               THE COURT:
                           There was some argument that there were
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- different kinds of braids.
- MR. SABER: Well, that's what Ms. Elderkin said.
- There's no evidence to support that. She said, well, you
- 4 could have a braid -- you know, she never disputed that the
- 5 braid is the two materials, you know, just like the hair
- braided together, right? What she said is, you could have a
- braid where there's a core, and then you have what's called a
- 8 sheath in the art, or a cover in the art, on the outside
- ⁹ which was braided of a different material. So the core would
- be one, and then the braid on the outside would be
- different. That's Ms. Elderkin's interpretation. Mind you,
- there's no evidence to support that, but that's what she
- 13 says.
- But even if we were to accept that, even if we were
- to accept that, in Burgess, there's not a word about a core.
- So the only thing that's left is a regular old braid that
- anyone would understand is just the two materials braided
- 18 together.
- THE COURT: Okay, thank you. Any quick response?
- Then I'm going to let you go.
- MR. BONELLA: Just quickly, your Honor, two
- points. One was, I heard Mr. Saber reading the statement
- that he was saying was a misrepresentation. I heard him
- paraphrase it, but then I heard him actually read it. When
- you actually read it, what it says is, "Even if he --" this

- is DMI 196 which is a prosecution entry -- "Even if he,"
- meaning a medical designer, "did use the teachings of the
- fishing line art to modify a suture, then he would inevitably
- design an unacceptable suture." It's about using teachings
- of fishing line art to modify sutures. Dr. Steckel never
- 6 testified about using teachings of fishing line art.
- ⁷ Mr. Saber kept saying that this response is PET plus
- 8 ultra-high molecular weight is an unacceptable suture. It
- 9 doesn't say that.
- If I could just respond to one thing he said about
- there's no evidence in the record about what a braided
- construction is. That's false. Dr. Hermes testified that
- the core sheath is a braided construction, but it's not in
- direct intertwining contact as claimed. Also Dr. Mukherjee
- agreed that the term "braided construction" which is in the
- Burgess application also (Inaudible) to the core sheath, and
- there are many, many other examples of --
- THE COURT: You're saying Burgess had a core
- 19 sheath?
- MR. BONELLA: Burgess says it's a braided
- construction, doesn't specify at all what the braided
- construction is, how to make it, how it's constructed, just
- says braided construction. It could be an infinite number of
- things.
- THE COURT: Thank you very much to all of you. Let

- 1 me just ask you. I just want to understand the process. If
- I say no infringement, it's over. You go up to the Federal
- 3 Circuit, right?
- MS. ELDERKIN: I believe that's right, your Honor.
- 5 THE COURT: If I say disputed issue of fact, I
- 6 agree with your analysis of the basic and novel, but I am
- 7 confused about the subtle versus the material, then would you
- 8 want to go to trial just on infringement, or are there
- 9 validity issues?
- MR. SABER: There are many validity issues, your
- Honor.
- THE COURT: So the thought would be one uniform
- 13 trial?
- MS. ELDERKIN: Yes.
- THE COURT: And what I would need to do is just set
- up a trial date?
- MS. ELDERKIN: Yes. Right now we're sitting with a
- November 13 trial date.
- MR. SABER: Though we've been told by Mr. Alba
- ²⁰ that --
- THE COURT: As a practical matter, unless my mega
- pharmaceutical case settles, that looks unlikely, so I don't
- want you flying people in. It's more likely to be the new
- year, if we should go that way, and, quite candidly, I'm not
- sure this opinion will be out by then, so --

Page 83 1 MR. SABER: Your Honor, I appreciate that 2 because -- I think actually counsel probably may actually 3 agree with this -- we're all from out of town, and to have a 4 date certain is really important to us, if we can. 5 THE COURT: I'm not sure I'll ever be able to give 6 you that because I've got drugs, guns, and child pornography. 7 MR. SABER: Sure, but as close as you can. THE COURT: The criminal is always going to trump 9 it somewhat. 10 MR. SABER: I completely understand that. 11 THE COURT: But I can usually get you -- I think 12 the odds are against a November trial date unless my 13 pharmaceutical case either settles or gets continued, but 14 we're sure going to let you know a lot in advance, and we 15 won't pull the last-minute thing on you. 16 MR. SABER: I appreciate that. 17 THE COURT: But what you really are telling me is that I need to -- if I say there's a fact question on 18 19 infringement, we should have a joint trial on infringement 20 and validity. 21 MR. SABER: That's correct, your Honor. 22 MS. ELDERKIN: Yes, your Honor. 23 THE COURT: And the issues are what, obviousness? 24 MR. SABER: There is anticipation and obviousness. 25 Good. Oh, we haven't even touched THE COURT:

- ¹ anticipation.
- MR. SABER: Well, you know, that's right, and we
- 3 could rely on our briefs on that. We don't want to take your
- 4 Honor's time. But as I'm sure you can appreciate, you know,
- we tried -- I think both sides, frankly, tried to be
- selective in what we presented to you on summary judgment.
- ⁷ If we go to trial, there are multiple other issues.
- 8 THE COURT: What else? Is there best mode or --
- 9 MR. SABER: There are some 112 issues, not a best
- mode issue, but there are some enablement issues --
- THE COURT: I'm most confused on enablement. Don't
- they usually want me to do that as a --
- MR. SABER: Well, those are fact issues for a jury,
- 14 and that's what the law is. Now, again, we tried to pick and
- 15 choose --
- THE COURT: Right, so there's the usual --
- MR. SABER: And there are several different prior
- art issues that are not in the papers.
- THE COURT: And what about damages?
- MR. SABER: There's those issues too.
- THE COURT: And these have all been teed up?
- You've done discovery into them and all that kind of stuff?
- MS. ELDERKIN: Expert report, expert discovery is
- completed, and everything's ready to go.
- THE COURT: All right. And inequitable conduct --

- 1 in other words, what really needs speedy attention are the
- claim construction and infringement, and I can maybe do
- inequitable conduct or not on the paper record, but that's
- 4 not what's deciding the lockstep on all of this.
- MS. ELDERKIN: Right. And as long as your Honor
- 6 agrees that inequitable conduct does not get presented to the
- ⁷ jury, there's no rush on that.
- 8 THE COURT: No, no, I usually do that. Sometimes
- 9 it takes as long as the jury trial, but -- and I like to do
- it afterwards because by then I've totally understood the
- technology a little bit better, although this has been a very
- useful heads-up and well argued. It's just I need to -- if I
- get to it, I get to it. If I don't, I don't. I need to get
- through your claim construction issues is the key piece of
- 15 this.
- MR. SABER: I agree. Those, I think, are the most
- important issues.
- THE COURT: And last but not least, have you
- 19 attempted a mediation on this?
- MS. ELDERKIN: Yes.
- MR. SABER: We did, your Honor.
- MS. ELDERKIN: We had a mediation about a month
- 23 ago.
- THE COURT: And it's hopeless until I start doing
- some of this stuff?

Page 86 1 MS. ELDERKIN: I believe so, your Honor. THE COURT: Now, once I resolve it, let's assume I 3 said -- I'm not saying I'm saying -- "Well, here's what it says the key inventive thing is, handleability, 5 blah-blah, but I don't know about coating, " would that facilitate a settlement? Would you want to go back? Or you 7 basically think that this case is going to have to go on a -you're not even close. I want to understand, if I make a 9 ruling on claim construction, does it make sense to send you 10 to mediation? 11 MS. ELDERKIN: Certainly if you rule in our favor, 12 your Honor. 13 THE COURT: If I rule in your favor -- I'm assuming 14 if I rule in either side's favor completely, it's just going 15 up on appeal at some point. But if I took this middle 16 ground --17 MS. ELDERKIN: Actually, you'll see in our papers, 18 even if you rule in their favor completely, we believe there 19 are still material issues of fact, genuine issues of material 20 fact that preclude summary judgment. 21 THE COURT: On infringement. 22 MS. ELDERKIN: On infringement. 23 THE COURT: No, no, no, I understand that fully. 24 I'm just saying, but that would be the gray area for both of 25 you where there might be a possibility for additional

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     settlement discussions or not?
               MS. ELDERKIN: It's always possible, your Honor.
 3
               MR. SABER:
                            That's a tough one to answer.
 4
     parties were very, very far apart.
 5
               THE COURT: Are you head-on-head competitors?
 6
               MS. ELDERKIN: Yes, your Honor.
 7
               THE COURT: So this isn't --
               MR. SABER: Well, in fact these parties have
     licensed each other in the past. You know, there's actually
 9
10
     an interesting dynamic here.
11
               THE COURT: Why don't we go off the record for
12
     this.
13
                (Discussion off the record.)
14
                (Adjourned, 4:00 p.m.)
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1
                     CERTIFICATE
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 3
     UNITED STATES DISTRICT COURT )
 4
     DISTRICT OF MASSACHUSETTS
                                   ) ss.
     CITY OF BOSTON
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               I, Lee A. Marzilli, Official Federal Court
     Reporter, do hereby certify that the foregoing transcript,
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     Pages 1 through 87 inclusive, was recorded by me
11
     stenographically at the time and place aforesaid in Civil
12
     Action No. 04-12457-PBS, DePuy Mitek, Inc. V. Arthrex, Inc.,
13
     and thereafter by me reduced to typewriting and is a true and
14
     accurate record of the proceedings.
15
               In witness whereof I have hereunto set my hand this
16
     24th day of October, 2006.
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